


	Title: QwikCheck™ DFI Kit Production Protocol			
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Certificate Of Analysis

Product Name: QwikCheck™ DFI Kit	Batch No.: 1873-140923
Product Catalog No.: A-CA-01873-00	Expiry Date: 30 th SEP 2024
Storage Condition: 2-25°C (36-77°F)	Test Date: 27 th SEP 2023

Kit Components:	Critical Attributes	Pass Results	Results Pass / Fail
Lys A Solution	Turbidity	Clear	PASS
	Color	Colorless	PASS
Lys A Powder	Color	White	PASS
Lys B Solution (Bulk)	Turbidity	Clear	PASS
	Color	Colorless	PASS
Diluent Solution	Turbidity	Clear	PASS
	Color	Colorless	PASS
Fixative Solution	Turbidity	Clear	PASS
	Color	Colorless	PASS
Giemsa A	Turbidity	Clear, no precipitation	PASS
	Color	Dark Blue	PASS
Giemsa B	Turbidity	Clear, no precipitation	PASS
	Color	Colorless	PASS
Functional Assay (performed with Normozoospermia sample)	Differential Halos	Clear differences in Fragmented and Non-fragmented sperms seen	PASS

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DFI Kit Batch Release Form				
Batch #: 1873-140923			Expiration Date: 30 th SEP 2024	
Item #	Component	Quantity	Description	Status
1	Diluent (for sample see chart)	1	15 mL wide mouth bottle	V
2	Low Melting Agarose (LMA) tubes	10	0.5 ml tubes	V
3	Agarose coated Slides	1	10-Slide Holder Boxes	V
4	Lys A Powder	10	2 mL amber vials	V
5	Lys A Solution	1	15 mL wide mouth bottle	V
6	Lys B Solution	1	15 mL Dropper bottle	V
7	Fixative	1	15 mL Dropper bottle	V
8	Giemsa A	1	15 mL Dropper bottle	V
9	Giemsa B	1	15 mL Dropper bottle	V
10	Coverslips 40mm x 22mm	1	10-Coverslip Holder box	V
QC Tests (manufacturing and Packaging QC performance)				Pass/Fail
APPROVALS				
Name	Position	Date	Signature	
S.Z	Clinical Research Assistant – Production and QC	27 th SEP 2023	<i>S.Z</i>	
A.T	Clinical Research Assistant – Packaging	28 th SEP 2023	<i>A.T</i>	
R.R	Clinical Manager	02 nd OCT 2023	<i>R.R</i>	
M.D	CEO	02 nd OCT 2023	MD	